

Remarks/Arguments

Claims 11 and 14-21 are pending.

Claim 11 has been amended to recite “wherein said osmolyte results in accelerated healing of the affected skin.” This is supported by page 4, paragraph 4 of the specification.

The rejection of claims 11, 14-21 under 35 USC 103(a) as being unpatentable variously over Motitschke et al. in view of Hanifin, Touito, and Loden is respectfully traversed.

Essentially, none of the prior art references, alone or in combination, show “wherein said osmolyte results in accelerated healing of the affected skin”, as claimed. For instance, Motitschke shows that it can improve moisturize dry skin (via forming a barrier on the skin surface or binding of water by the compound); and Loden merely shows that urea can improve the skin barrier function and reduce skin susceptibility to irritants. None of the prior art disclose or suggest that their inventions are capable of resulting in “accelerated healing of the affected skin.”

With regards to Motitschke mentioning treating individuals with atopy, he states the following:

“A major task of cosmetics is the preservation or restoration of the normal state of the skin. In addition to other criteria, stabilizing the moisture content of the skin plays an important role. Under normal conditions, the skin itself is capable of regulating its moisture content. A change in the external environment, such as, for example, a cold dry atmosphere, very rapidly results in the state in which the skin surface is dried out. The surface of the skin turns flaky and tends to chap slightly. The skin is highly sensitive to chemical and physical factors. In patients suffering from atopy, these skin symptoms are observed irrespectively of the age, while, in healthy humans, the dry skin condition becomes more

pronounced as they grow older (B. Idson, Cosmetics & Toiletries, 107 (1992), pages 69-78). This skin condition can be prevented as well as counteracted by using suitable moisturizing preparations.” (see col.1, paragraph 3; emphasis added).

From the above, a person of skill in the art would only interpret that Motitschke work was relevant only to treating the ‘dry skin’ symptoms even in those individuals suffering from atopy and not treating atopy itself; and certainly, it would not have been obvious that Motitschke was aware that their application would have resulted in accelerated healing of the affected skin, as claimed. Indeed, the examples in Motitschke only show that they measured a) water absorption capacity and b) hydration of the skin (see col.6).

In contrast to the cited prior art applicants work is based on the insight that ectoine usefulness as treatment of neurodermatitis is - not due to its moisturizing properties but - due to its anti-inflammatory properties. Hence, it can be compared to glucocorticosteroids, however, without the negatives side effects that are associated with the use of steroids. In contrast to that Motitschke merely discloses the use of ectoine as a moisturizer. Hanifin shows that the effectiveness of steroids can be enhanced by use of a moisturizer, but does not disclose the use of a moisturizer alone. Finally Loden discloses the use of one certain moisturizer, namely urea, alone for the treatment of atopic dermatitis. However, this does not automatically make obvious the use of other moisturizers since even Loden mentions that moisturizers are not identical with regard to composition or effects on the skin (cf. page 264, last sentence of the first column to first paragraph of the second column). Accordingly, only “certain” moisturizers can be used (cf. summary).

Even more important Loden merely shows that urea can improve the skin barrier function and reduce skin susceptibility to irritants. In contrast to that treatment of neurodermatitis by ectoine by the applicant goes far beyond simple treatment of dry skin by improving the barrier function but attacks the causes of neurodermatitis. Ectoine and hydroxyectoine have similar antiinflammation properties as

glucocorticoids but avoid their negative side effects. In fact, it was possible to show that ectoine/hydroxyectoine block the release of the inflammation messenger interferon γ by lymphocytes.

With respect to the antiinflammation properties of ectoine please find attached paper of Sydlik et al.: "The Compatible Solute Ectoine Protects against Nanoparticle-induced Neutrophilic Lung Inflammation", Am J Respir Crit Care Med. 2009, 180, 29-35. Antiinflammation properties of ectoine were shown with lung epithelial cells. Although this inflammation is different from neurodermatitis it is comparable since the lung and the skin consist of epithelial cells. Moreover, inflammation pathways are similar. e.g. Figure 5 on page 33 shows that ectoine prevents neutrophil inflammation *in vivo*. This is shown with the lavage parameters % neutrophils and cinc-1. In contrast to that, as can also be seen from page 33 left column, urea, which is one of the most effective moisturizers, had no effect on inflammatory parameters and does not prevent neutrophil inflammation. This clearly shows that the moisturizing properties of certain compounds are totally different from the antiinflammation properties.

Accordingly, Loden's work on atopic subjects with the urea based moisturizer would not have resulted in accelerated healing of affected skin nor would it have been obvious from Loden that other moisturizers (such as ectoine) would similarly accelerate skin healing, as claimed. Moreover, please note that the very common moisturizer urea is not well tolerated by many patients suffering from neurodermatitis. Indeed, with respect to the remark that urea is not well tolerated by many patients suffering from neurodermatitis please also note that Loden says on page 267 that concerns were expressed regarding the use of urea. Moreover, Loden mentions that certain humectants show keratolytic properties. Accordingly, this shows that not every moisturizer is effective in treatment of neurodermatitis even with respect to merely improving the water barrier function.

The rejection of claim 21 is, in addition to the above arguments, independently traversed. Certainly, Hanifin does not disclose that moisturizers alone (without Hanifin's corticosteroid) are effective in the treatment of atopic dermatitis.

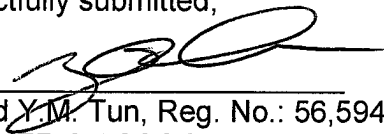
Accordingly, a person of skill in the art would not necessarily be motivated to test ONLY moisturizers for treating atopic dermatitis.

No other issues remaining, applicant believes the claims are all in condition for allowance and respectfully solicits a Notice of Allowance.

The Commissioner is hereby authorized to charge payment of any fees required associated with this communication or credit any overpayment to Deposit Account No. 50-3881. If an extension of time is required, please consider this a petition therefor and charge any additional fees which may be required to Deposit Account No. 50-3881.

Dated: January 10, 2011

Respectfully submitted,

By 

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